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10/659,930	09/11/2003	Wayne E. Cornish	ACS 65357 (1512XCC)	5064

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FULWIDER PATTON LEE & UTECHT, LLP
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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,930

Applicant(s)

CORNISH ET AL.

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007 and 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment to claim 67 and the amendments to the specification are acknowledged.

Specification

2. The amendment filed 10/15/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the new paragraphs describing figure 17. Applicant notes that these amendments can be found in US 6,390,993. However, this is insufficient to show that the amendments are supported. It appears that figure 17 and the associated description in the specification were not originally disclosed in the parent case (09/203,140, now US 6,390,993). Applicant needs to show that the amendments are supported in the original disclosure of US 6,390,993 or cancel the new matter (including figure 17 itself) in the reply to this Office Action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 64-68, 70-74, 76-81, 83 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Amplatz et al. (US 4,991,602).

5. Amplatz discloses a guidewire comprising an elongated member having means (the tapered segments around 12, 22 and 24 in figure 2) for causing a substantially linear change in bending stiffness over a relatively short longitudinal length of the elongated member. It is well known in the art that non-linear curves will appear substantially linear when only considered over a relatively short length. Therefore, the tapered segments of the Amplatz guidewire are considered to cause a substantially linear change in bending stiffness when considered over only a relatively short longitudinal length of the elongated member.

6. In regards to claim 65, the taper angle continuously changes near 22 in figure 2 producing a curvilinear profile. In regards to claims 66 and 67, the elongated member has a plurality of tapered segments (12), each having a constant taper angle. In regards to claim 68, the elongate core member has at least three tapered segments as noted above. In regards to claim 70, the elongated member tapers distally (around 12 in figure 1) to a more flexible distal portion.

7. At a length L equal to zero from a starting diameter D_0 , the diameter of the guidewire corresponds to the equation set forth in claim 71. At a length L equal to zero from a starting diameter D_0 , the moment of inertia of the guidewire corresponds to the moment of inertia set forth by the equation in claim 78. The claimed equations

significantly simplify when $L=0$. When solved for only $L=0$, the prior art guidewire reads on claims 71 and 78.

8. In regards to claims 72 and 79, the core member is formed of Nitinol (column 2, lines 30-32). In regards to claims 73, 74, 80 and 81, the core member may be coated with a lubricious coating (column 5, lines 15-25). In regards to claims 76, 77, 83 and 84, the guidewire comprises at least 6 tapered segments (12, 22, 24 on each end of the guidewire).

9. Claims 64, 66-72, 75-79 and 82-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Urick (US 5,497,786).

10. Urick discloses a guidewire comprising an elongated member having a plurality of tapered segments (12, 14, 16, 18). It is well known in the art that non-linear curves will appear substantially linear when only considered over a relatively short length. Therefore, the tapered segments of the Urick guidewire are considered to cause a substantially linear change in bending stiffness when considered over only a relatively short longitudinal length of the elongated member.

11. In regards to claim 66-68 and 70, the tapered segments each have a substantially constant taper angle and taper to a more flexible distal portion. In regards to claim 69, Urick discloses a material with changing hardness (30 in figure 3).

12. At a length L equal to zero from a starting diameter D_0 , the diameter of the guidewire corresponds to the equation set forth in claim 71. At a length L equal to zero

from a starting diameter D_0 , the moment of inertia of the guidewire corresponds to the moment of inertia set forth by the equation in claim 78.

13. In regards to claims 72 and 79, the core member is formed of stainless steel (column 2, lines 44-49). In regards to claims 75 and 82, a flexible body (26) is disposed about and secured to a distal core section. In regards to claims 76, 77, 83 and 84, the guidewire comprises at least 5 tapered segments (12, 14, 16 and 18 as shown in figure 1 and on each side of 19 as shown in figure 3).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

16. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 64, 66-68 and 71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 13-15, 21, 28, 39 and 42 of U.S. Patent No. 6,673,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite all of the features of the broader claims of the instant application. Therefore, the instant claims are "anticipated" by the patented claims and are not patentably distinct from the patented claims. Instant claim 64 corresponds to patented claims 13, 28, 39 and 42. Instant claims 66-68 correspond to patented claims 14 and 15. Instant claim 71 corresponds to patented claims 21 and 42.

18. Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 and 62 of copending Application No. 10/631,275. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the copending claims recite all of the features of the broader claim of the instant application. Therefore, the instant claim is "anticipated" by the copending claims and is not patentably distinct from the copending claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Terminal Disclaimer

19. The terminal disclaimer filed on 10/18/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,666,829 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

20. Applicant's arguments with respect to the 35 U.S.C. §112, first paragraph rejection of claim 64 have been fully considered and are persuasive.

21. Applicant's arguments with respect to the prior art rejections have been fully considered but they are not persuasive.

22. Applicant argues that a short segment relied upon in the rejections could be redrawn using a different scale that would clearly show that the segment is not linear at all. In response, the different scale required to show that a short segment is non-linear would be miniscule relative to the overall change in the bending stiffness of the entire elongated member. Therefore, a relatively short segment is considered to have a

substantially linear change in bending stiffness *in relation to the overall change* in bending stiffness of the elongated member, which is sufficient to read on the present claim language. For example, Applicant's figure 12 shows a typical change in bending stiffness of a prior art guidewire. If you consider only a length between two consecutive points on the plot, the change between the consecutive points appears *substantially linear* relative to the plot as a whole.

23. In regards to claims 71 and 78, Applicant argues that when $L=0$, there is no length to the elongate core member and therefore that portion of the guidewire does not exist. In response, the application of $L=0$ to the claimed equations does not require that the longitudinal section has no length. Instead, the longitudinal section of a non-zero length has a *diameter* at a single point defined by the claimed equations when $L=0$.

24. Applicant argues that the double patenting rejection based on US 6,673,026 and application 10/631,275 do not anticipate any of the current claims because US 6,673,026 and application 10/631,275 do not constitute prior art to the current application. In response, the use of the word "anticipate" in the rejections is intended to show that the claim(s) of US 6,673,026 and application 10/631,275 read on the current claim(s) regardless of any dates. Therefore, the obviousness type double patenting rejections based on US 6,673,026 and application 10/631,275 are maintained.

Conclusion

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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